K122940

MAR 19 2013

5. 510(k) Summary

Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter
510(k) Summary
21 CFR 807.92
Date Prepared: March 19, 2013

Submitted By:

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Device Information:

Trade name:	Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter
Common name:	PTA Balloon Catheter
Classification:	Class II
Regulation:	21 CFR §870.1250
Product Code:	DQY, LIT

Predicate Device:

Advance 14LP Low Profile PTA Balloon Dilatation Catheter

D.C. #K090822, April 27, 2009

Cook Incorporated
Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter Traditional 510(k)

Device Description:

The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is an over-the-wire catheter available with an inflated balloon diameter of 1.5 mm with balloon lengths of 2 and 4 cm and balloon diameters of 2, 2.5, and 3 mm with balloon lengths of 2, 3, 4, 6, 8, 10, and 12 cm. The catheter is 2.5 French in outer diameter with a length of 50, 90, or 150 cm. The catheter is compatible with a 0.014 inch (0.36 mm) diameter wire guide. It will be supplied sterile, intended for one-time use.

Intended Use:

The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including internal pudendal, iliac, renal, popliteal, femoral, iliofemoral, anterior tibial, posterior tibial, peroneal, pedal, radial, brachial, and ulnar, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary arteries.

Discussion of Tests and Test Results:

The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Balloon Minimum Burst Strength – Testing shows the balloons will burst at or above the minimum rated burst pressure, with all failure modes being linear tears. The predetermined acceptance criteria were met.
2. Balloon Preparation and Simulated Use – All materials withstand contact with saline/heparin and contrast medium (1:1 ratio) during simulated use. Simulated use testing shows the devices are compatible with the recommended introducer and wire guide and perform according to the instructions for use. The predetermined acceptance criteria were met.
3. Catheter Diameter and Balloon Profile – Measurement of the diameter of catheter shaft, bonds, and folded balloon shows that the device profile is less than 1.016 mm (0.040 inch). The predetermined acceptance criteria were met.

4. Balloon Compliance – Testing shows that, under simulated body temperature conditions, each balloon will meet its labeled diameter within tolerance at the nominal pressure. The predetermined acceptance criteria were met.
5. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation, withstanding 10 cycles of inflation/deflation. The predetermined acceptance criteria were met.
6. Bond Strength – Testing shows the tensile force during proper clinical use should not fracture or rupture the balloon catheter bonds. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.
7. Inflation / Deflation Time – Testing shows that the balloon will inflate to rated burst pressure within 60 seconds and fully deflate within 60 seconds. The predetermined acceptance criteria were met.

Conclusions Draw from the Tests:

The results of these tests provide reasonable assurance that the device is as safe and effective as the predicate device and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Cook Incorporated
c/o Ms. Elysia Easton
Regulatory Affairs Specialist
750 Daniels Way, PO Box 489
Bloomington, IN 47402-0489

Re: K122940
Trade/Device Name: Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, LIT
Dated: February 13, 2013
Received: February 14, 2013

Dear Ms. Easton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K122940

Device Name: Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter

Indications for Use:

The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including internal pudendal, iliac, renal, popliteal, femoral, iliofemoral, anterior tibial, posterior tibial, peroneal, pedal, radial, brachial, and ulnar, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary arteries.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner